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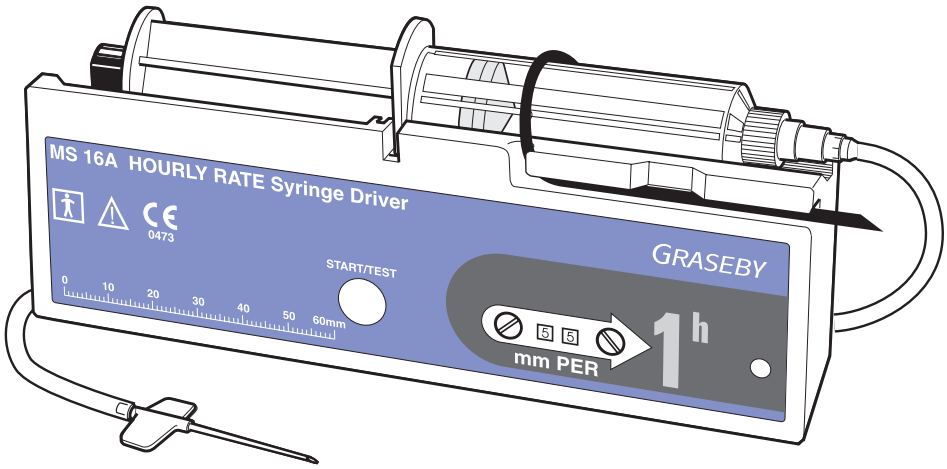
Graseby® MS16A
Syringe Driver



Technical Service **Manual**

CE 0473

Part Number 00SM-0105-6
Issue 6 (February 2005)

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Issue No.	**Reason for change**	**Pages effected**	**Date**
5	Re-issue of Manual	All	May 2000
6	Lockbox and US variants added. Corporate i.d. change.	All	February 2005

Scope of this manual

This manual enables service personnel to service and repair the MS16A Syringe Driver. It has been updated to incorporate Lockbox information and the US variant.

Related manuals

Refer to the following Instruction Manual when more detailed operating information is required. The Service Manual contains basic driver operation information only.

- MS16A Syringe Driver, MS26 Syringe Driver Instruction Manual, *part number 0105-0549-A*

Smiths Medical service contacts

In the event of any queries or problems that cannot be resolved by this manual, please contact the appropriate Service/ Repair Centre.

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Warnings

Warnings tell you about dangerous conditions that may occur, and which could lead to death or serious injury to the user or patient if you do not obey all of the instructions in this manual.

1. **Remember the rate is set in milliMETRES *NOT* milliLITRES. The correct rate is essential to prevent serious injury or death to the patient.**
2. **Any damaged pumps must be thoroughly tested by a competent person in accordance with the procedures in this service manual before re-use with a patient. Failure to observe this may result in patient injury or death.**
2. **Completely prime the administration set, and remove all air from both the administration set and the syringe before measuring the mm of fluid length, otherwise the rate calculation will be incorrect.**
3. **The driver must only be used with the syringe rubber securing strap fixed firmly in place, thus preventing an uncontrolled infusion to the patient that could result in serious injury or death.**
4. **Never take a syringe that is not empty off the driver if it is still connected to the patient. The infusion line must first be clamped or disconnected to prevent serious injury or death to the patient.**
5. **The use of spare parts other than those recommended is not advised, and may affect the correct operation of the driver, resulting in injury or death.**
6. **The syringe driver must not be used for infusing medication where pulsatile delivery action is unacceptable.**
7. **The syringe driver must not be used in environments with flammable gas mixtures or with oxygen-enriched atmospheres.**
8. **If the syringe driver is used in the lockbox, the alarm volume will be reduced.**

Cautions

Cautions tell you about dangerous conditions that can occur which may cause damage to the pump if you do not obey all of the instructions in this manual.
A damaged pump must never be put into active service, as it may be a hazard to patients through under- or over-infusing.

1. **To prevent serious damage to the driver it must *not* be immersed in any liquids or exposed to strong organic solvents. If immersion occurs or the driver is subject to a serious spillage or wetting incident, it must be thoroughly tested by a competent person in accordance with the procedures in this service manual before re-use with a patient.**
2. **Wipe off spills immediately. Do not allow fluid or residues to remain on the pump.**
3. **The pump is not designed to be autoclaved, steam-sterilised, ETO sterilised or subjected to temperatures in excess of 45° C (113° F). Failure to observe this caution may cause serious damage to the pump.**
4. **To avoid possible malfunction of the pump, do not expose the pump to X- rays, gamma rays or other ionizing radiation, or to the RF interference or strong electric / magnetic fields emitted (for example) by arc welding equipment or mobile transmitting equipment.**
5. **Moving parts of the driver do not require lubrication during their lifetime. Worn or stiff parts should be replaced.**
6. **Handling the printed circuit board is required during disassembly/ assembly. A static controlled work station including a conductive mat and grounded wrist strap should be used to provide protection against electrostatic discharge (ESD) or circuit board damage could result.**
   Take care to avoid contamination of the exposed switches, circuit tracks and components, e.g. by the entry of solder particles.
7. **Refer all service, repair, testing and calibrations to suitably qualified technical personnel. Unauthorised modifications to the driver must not be carried out.**
8. **Federal law restricts these Syringe Drivers for use by or on the order of a physician. This applies to drivers distributed *only* within the United States.**

Glossary

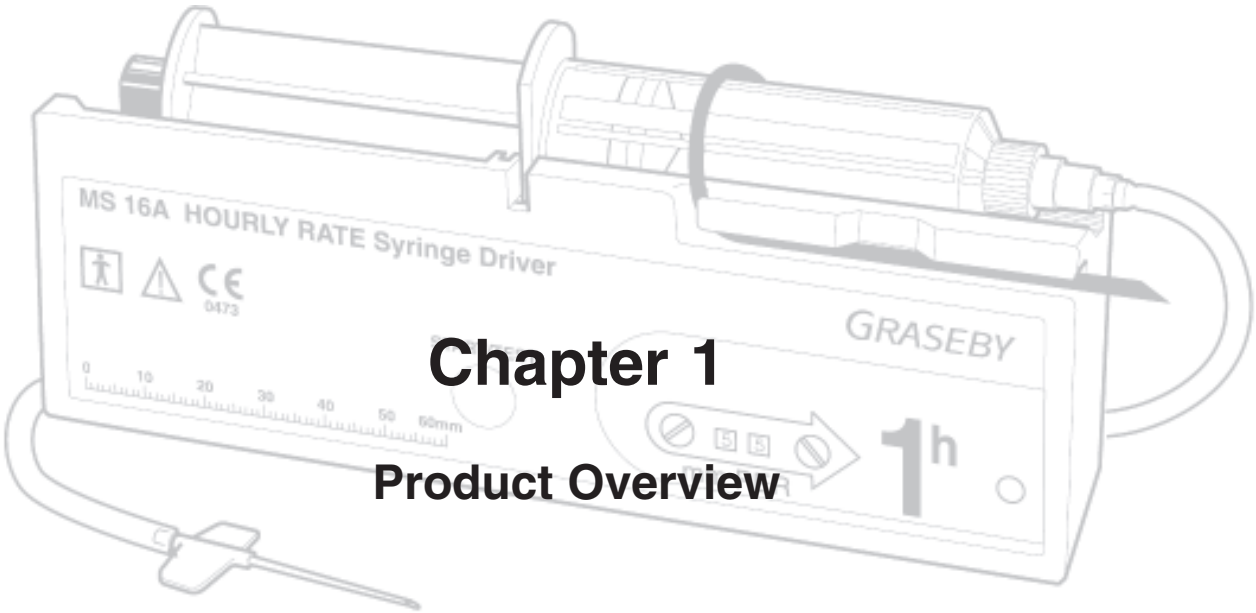
Abbreviations

The following abbreviations are used in this Manual.

Abbreviation	Meaning
ABS	Acrylonitrile Butadiene Styrene
C	Centigrade or capacitor
cNm	Centinewton metre
DC	Direct Current
gm	grams
h/hr	hour
hPa	Hectopascal (=100 pascals)
IC	Integrated Circuit
Kg	Kilogram
Kgf	Kilogram force
KHz	Kilohertz
LED	Light Emitting Diode
ml	Millilitre
mm	Millimetre
N	Newton
PCB	Printed Circuit Board
R	Resistor
RH	Relative Humidity
Sec	Second
SW	Switch
TR	Transistor
V	Volts

Graseby® MS16A

Syringe Driver



Chapter 1

Product Overview

Chapter 1 - Product Overview

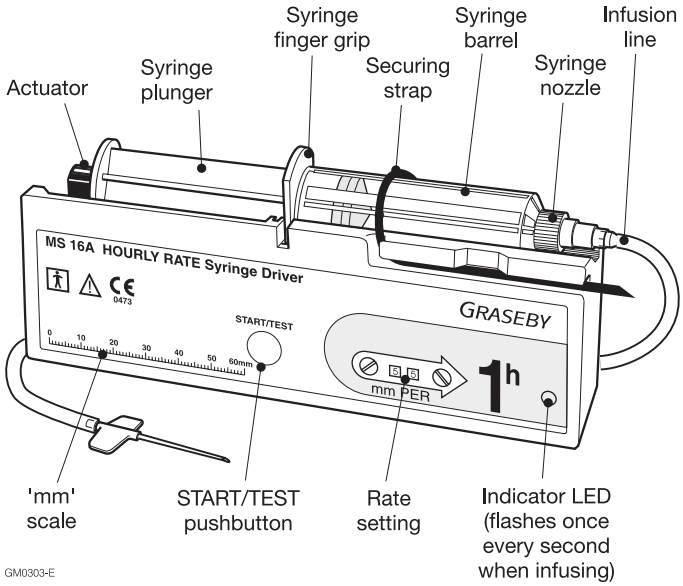


Figure 1-1 MS16A Hourly rate syringe driver

Description

The MS16A Syringe Driver (*Figure 1-1*) is a portable, battery-operated device, designed for the continuous infusion of small volumes of liquid from commercially available disposable syringes. The driver operates over time spans ranging from less than 30 minutes to 60 hours.

The syringe plunger is operated by a linear actuator, at rates ranging from 1 to 99 mm/hour (**mm PER**). The rate required is set by adjusting two digital rotary switches.

Most brands of syringe can be fitted to the driver, and the volumetric delivery depends on the size of the syringe being used. A millimetre scale is provided on the front of the driver to measure the stroke length of the syringe, so that the rate in mm/hour may be calculated.

For added security, the syringe driver can be secured in a transparent plastic, lockable box (see *Figure 1-2*).
When fitted, the box minimises the risk of tampering with the infusion.

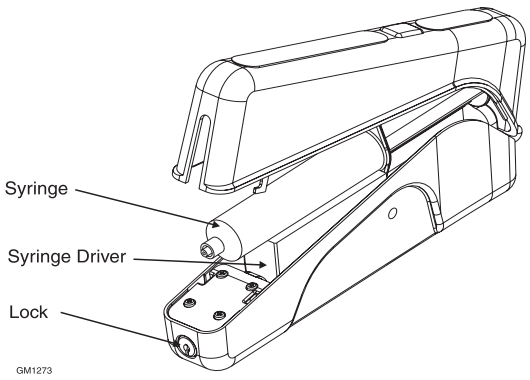


Figure 1-2 Lockbox

The clear plastic lockbox is hinged at the back and features a lock at the front. The syringe is held in place on the driver by the securing strap and the infusion line passed through the slot at the front of the box. When the **mm PER** setting has been selected and the **START/TEST** pushbutton pressed, the loaded driver is located in the box which is then locked. The patient controls (*Figure 1-3*) may be viewed through the clear window at the side of the lockbox.

Controls

Patient controls (*Figure 1-3*) consist of two rotary set rate **mm PER** slotted switches, and a **START/TEST** pushbutton.

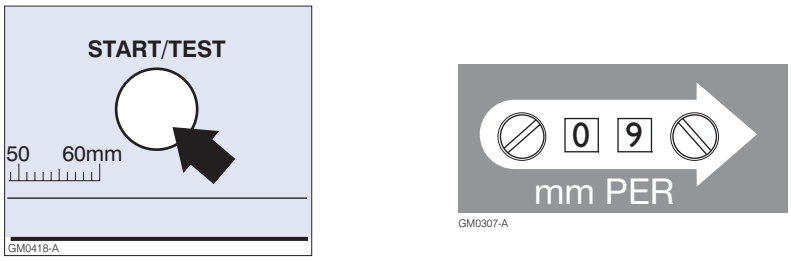


Figure 1-3 MS16A Controls

Operation

Note: For detailed operating information, refer to the MS16A, MS26 Instruction Manual, *part number 0105-0549*.

To start an infusion, fit a primed syringe and press the **START/TEST** pushbutton.

When held down, the **START/TEST** pushbutton tests a safety cut-out circuit. When released, it starts the drive circuit. Once started, the front panel LED flashes approximately every second.

When the plunger reaches the end of travel (syringe empty) or is occluded, the driver switches off, the LED stops flashing and an audible alarm sounds.

If the **START/TEST** pushbutton is held down for more than 3 seconds, the alarm sounds, the driver stops and the LED stops flashing.

If required, the driver can be modified to sound a continuous tone when the driver stops. See Chapter 6, Maintenance for modification instructions.

For additional protection, the syringe driver can be secured in a Lockbox.

Packed set

The MS16A packed set (*part number 0105-0504*) is supplied with the following items:-

1. MS16A Syringe Driver.
2. Battery, type IEC 6LR61.
3. Instruction manual.
4. Rate adjuster.
5. Shoulder holster (not US version).
6. Clear cover (not shown).

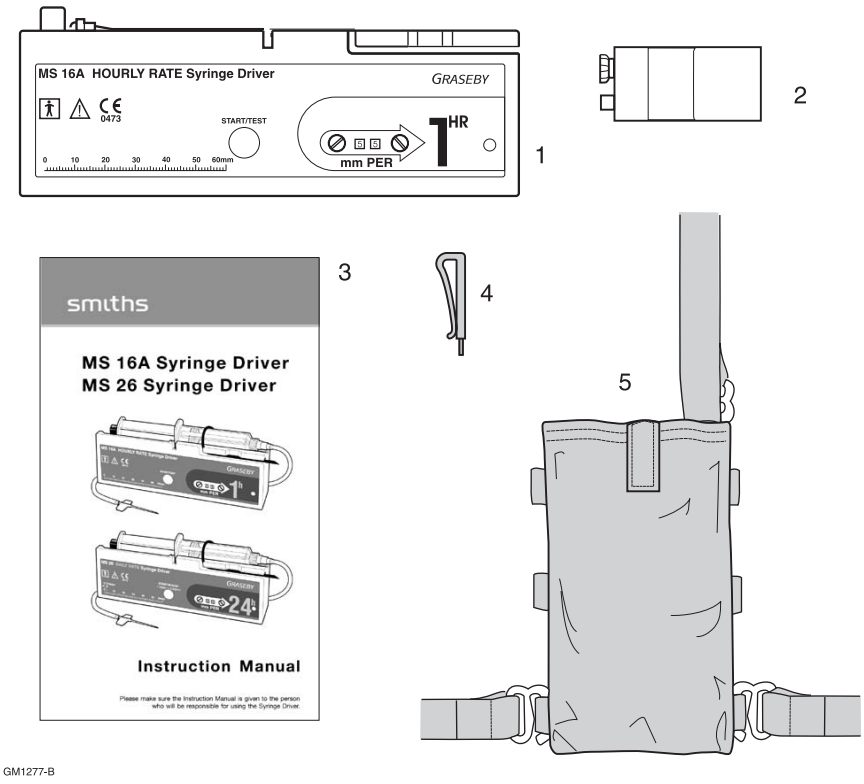
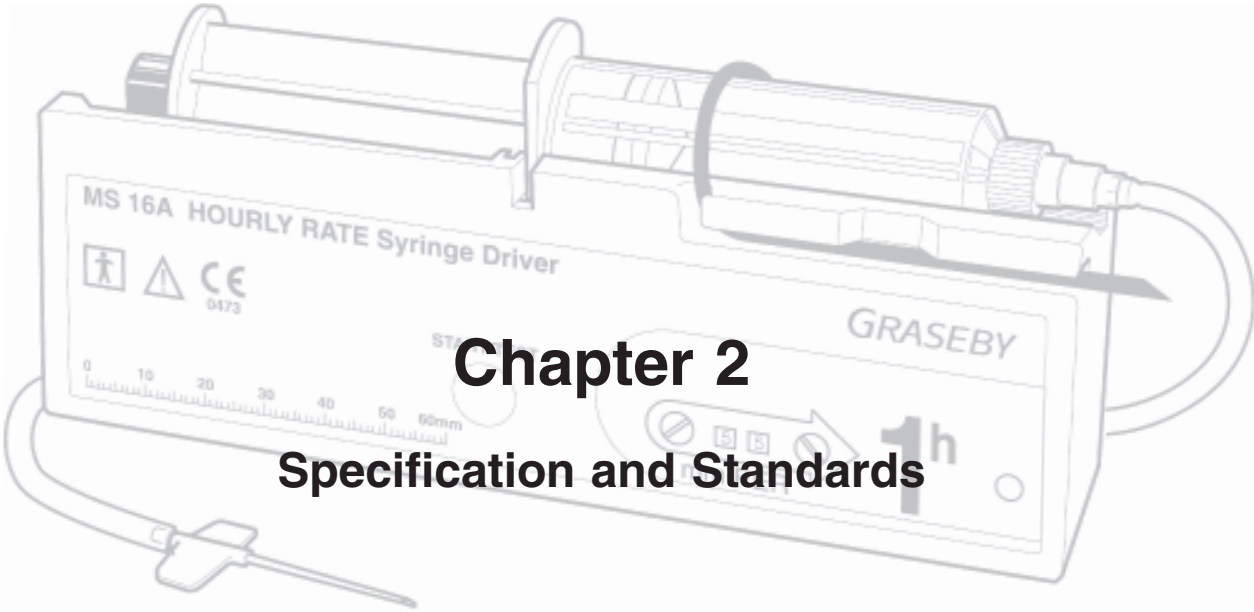


Figure 1-4 Package contents

Accessories and consumables

Item	Description	Part number
100 cm infusion set	PVC line with 25 gauge needle.	0105-0029
Subcutaneous infusion pack	BD 10 ml syringe, Tegaderm dressing alcohol wipe, transfer needle, 100 cm infusion set.	0105-0117
Syringe driver non-slip base	Provides a secure base to stand the syringe drive on a flat surface.	0105-0108
Cover	Clear rigid plastic to protect the syringe driver and syringe.	0105-0529
Holster	Washable, soft fabric holster with cover	0105-0027
Instruction manual	Instructions for use. Guide to subcutaneous analgesia, technical and performance specifications.	0105-0549
Rate adjuster	Tool to turn slotted rate switches.	0105-0023
Training pack	A full package of presentation, instruction and testing materials.	TPF-00130
Lockbox	A transparent plastic, lockable security container (includes two keys). See page 1-3.	0105-0640

Graseby® MS16A
Syringe Driver



Chapter 2

Specification and Standards

Chapter 2 - Specification and Standards

Type:

Syringe driver with motor driven linear actuator, pulsed motion. Internal 9 V alkaline battery power source. Digital electronic rate control.
Automatic switch off when the syringe is empty.

Infusion time:

< 30 min. - 60 hours

Rate range:

Variable delivery rate of 0 - 99 mm/h in steps of 1 mm/h.

Motor operating interval:

420 ÷ rate = seconds

Drive accuracy:

The accuracy of the linear drive mechanism that pushes the syringe plunger forward: ± 5%

Drive force:

The force the linear drive mechanism that pushes the syringe plunger forward can produce: >3 Kg

Actuator movement:

0.12 mm every time motor turns.

Actuator stroke:

60 mm available (depends on syringe).

Syringe sizes:

2 ml to 35 ml

The holster supplied will enclose most types of syringe up to 20 ml capacity.

Occlusion pressure:

3 - 5 Kg

Maximum actuator force 50 N (5 Kgf) @ 9 V

Controls:

START/TEST and **mm PER** rate adjusters (tens and units digit controls).

Alarm:

Audible frequency:	3 kHz ± 0.5 kHz (end of travel: occlusion).
Duration:	5 - 20 secs.
Volume:	Audible at 1m with normal or corrected hearing

Indicator:

Low battery level: 7.0 V to 5.5 V (LED stops flashing)
Flash period: 1.05 secs ± 2%
Yellow solid state LED
Green solid state LED (US)

Battery type:

PP3 size. 9 V, primary alkaline, IEC 6LR61 (or 6LF22) type.
(Duracell MN1604 recommended)

Battery life:

50 full deliveries depending on the operating conditions and battery condition.
Automatic switch off at end of plunger travel.

Accuracy of delivery:

The rate of the actuator is accurate to within plus or minus 5% of the rate set on the rotary switches.

Dimensions (without syringe):

Height:	53.0 ± 0.5 mm
Width:	166.0 ± 1.0 mm
Depth:	23.0 ± 1.0 mm

Weight (including battery):

190 gm.

Operating conditions:

+10° C to +40° C. 30% to 75% RH (non-condensing).
700 hPa to 1060 hPa

Transport and storage conditions:

-40° C to +70° C. 10% to 100% RH (non-condensing).
500 hPa to 1060 hPa

Materials:

Case and battery cover - ABS RTA 50 injection moulding.
Labels - 125 micron fine matt Lexan.
Other materials - nitrile rubber, small plastic parts - Acetal (25% glass filled Kemetal) and PA-GF (glass-filled nylon).
Metal parts - stainless steel, mild steel.
Circuit board - epoxy glass fabric.
Holster - elasticated soft-backed fabric.

Note: All materials used in this product are latex free.

Standards

Electrical safety:

Complies with EN 60601-1: 1990 (IEC 601-1:1988).
Type BF Applied Part for protection against electric shock.

EMC:

Complies with EN 60601-1-2:1993 for emissions and immunity to electromagnetic disturbances. Group 1 Class B for emitted RF radiation according to EN 55011:1991 making it acceptable for use in domestic establishments.

Complies with RTCA DO-160D (Operation in a commercial aircraft with controlled pressurised cabin area which maintains cabin pressure at normal cabin environment.) Smiths Medical International Ltd. ref. CIB B1100.

Biological evaluation:

Complies with EN 30993-1:1994 Biological evaluation of medical devices - Part 1: Guidance on selection of tests.

Packaging:

Complies with EN 20780:1993 Packaging - Pictorial marking for handling of goods.

Medical device directive 93/42/EEC:

CE marked under Annex II, risk class IIb (active medical device).
Notified Body: AMTAC (0473).

Quality system standards used:

EN ISO 9001 and EN 46001.

Symbols

An electrical safety classification in the international safety standard for medical electrical equipment, Type BF. If the equipment is used as intended there is no risk of a serious electric shock. But it is not suitable for direct connection to the heart.

Refer to the accompanying instructions on how to use the equipment.
Detailed instructions on how to use the syringe driver are given in the Instruction Manual, *part number 0105-0549*.

The CE mark demonstrates that the Syringe Driver conforms to the requirements in the European Council Directive 93/42/EEC concerning medical devices.
The number 0473 identifies the Notified Body under which the Quality Systems operated within Smiths Medical are assessed.

Disposal

When disposing of the driver or its accessories do so in the best way to minimise any negative impact on the environment.

The internal battery contains harmful substances. First discharge the battery. Do not open up the battery, or incinerate it as it could explode.

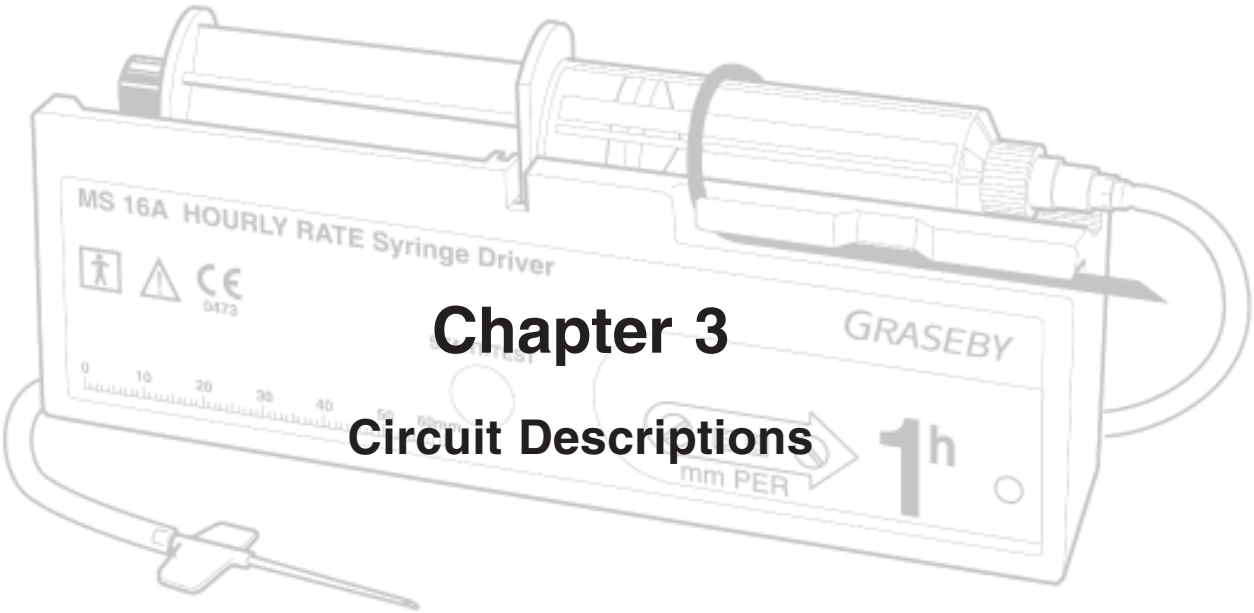
Contact your local waste disposal service to find out about special recycling or disposal schemes.

Separate any other parts of the driver where arrangements can be made for their recovery, either by recycling or energy recovery.

Important:
Existing national or local regulations concerning waste disposal must take precedence over this advice.

Graseby® MS16A

Syringe Driver



Chapter 3

Circuit Descriptions

Chapter 3 - Circuit Descriptions

Refer to *Figures 3-1, MS16A Circuit diagram* and *3-2, MS16A Printed circuit board layout*.

Logic

The Custom Integrated Circuit IC1 contains a very low power oscillator, which operates at a fixed frequency. The output of the master-clock is fed into a divider chain, which includes binary-coded switches SW4 and SW5, so that rates over a 99:1 range can be selected.

IC1 also contains the switching electronics which control the Start, Motor Drive and Guard circuits.

Start

The battery return line (0V) is switched by transistor TR3, which is controlled from pin 11 of IC1. This control is reset by a negative-going pulse at IC1, pin 10. Since IC1, pin 10 is biased low through resistor R2, the negative-going pulse is provided in the transition period during operation or release of the **START/TEST** button (SW1).

Diode D1 (a low voltage-drop type) protects the circuit components from damage if the battery polarity is reversed.

Motor drive

In the operation mode, IC1, pin 21 produces a square-wave pulse train, the frequency of which is determined by the setting of the Set Rate rotary switches SW4 and SW5. When the output from IC1, pin 21 goes high, transistor TR2 is turned on and TR1 is turned off.

With the cam-operated switch (SW3) in the position shown in *Figure 3.1*, the motor circuit is completed via TR2, and the motor runs until the cam operates the switch S3, (1/6 revolution). Because TR1 is turned off whilst TR2 is conducting, the motor circuit is broken and the motor stops (perhaps after some overrun). When the output from IC1, pin 21 goes low, transistor TR2 is turned off and TR1 is turned on.

The motor circuit is now completed via TR1 and the motor runs until the cam-operated switch (SW3) returns to its original position (another 1/6 revolution). Because TR2 is turned off whilst IC1/21 remains low, the motor circuit is once again broken until the next high output from IC1, pin 21 restarts the sequence.

Since each motor pulse results in 1/6 of a revolution of the leadscrew, the actuator advances the syringe plunger by 1/6 of the thread pitch, that is by 0.117 mm.

Note: The amount of overrun at each step, though indeterminate, is non-cumulative. After 60 pulses the cam will have rotated through ten revolutions plus the error of the last step.

Transistor TR4 and its associated components form an adjustable current regulator which is pre-set to limit the torque of the motor and therefore the maximum actuator thrust. Because the motor drive pulses may be quite infrequent, a light emitting diode (**LED**) is driven at a fixed frequency by IC1, pin 14. This provides a continuous check on the functioning of the oscillator and the low battery indication (see *Low battery indication, page 3 - 5).*

Primary guard

Whenever the motor is energised (i.e. whenever the node marked Ⓐ is held low), this is sensed at IC1, pin 22. If Ⓐ is held low for more than 3.7 seconds (896 cycles of the master-clock). the output from IC1, pin 11 causes TR3 to switch off.

In normal use, the motor runs for less than 3.7 seconds, so the guard circuit only operates when the motor is stalled (e.g. when the syringe is empty or when the delivery line is occluded), if a transistor or the cam-operated switch fails, or when the **START/TEST** pushbutton is held depressed.

Secondary guard

If the main oscillator ever fails, the run time of the motor is limited by a secondary guard circuit.

When the motor is energised, capacitor C2 acquires a charge via resistor R4 (the charge is quickly dissipated at the end of the motor drive pulse by diode D4).

If the motor attempts to run for longer than approximately 5 seconds, the voltage on capacitor C2 (i.e. voltage at IC1, pin 9) falls to a critical level, causing the output from IC1, pin 11 to switch off TR3.

The driver will fail safe (switch off), regardless of how Ⓐ came to be held low for longer than the normal operating pulse duration.

Switch-off alarm

The piezo-transducer (X1) and associated components (TR8, R18, R15, R16) are arranged so that an alarm tone sounds when the bottom end of R16 is held low. This occurs for a few seconds whenever TR3 switches off, owing to TR9 being turned on until C5 is charged via R17.

Test circuit

When the **START/TEST** button is pressed and held, TR3 is turned on by switch S1 (see *Start, page 3 - 1*) and the motor circuit completed via switch S2. The motor runs until it is switched off by the primary guard circuit. When the button is released, the syringe driver resumes the normal drive mode.

Safety features

Part of the circuit associated with pins 9, 10, 11 and 12 operates, via TR3, to allow the operation of the driver only while safe conditions exist. A crucial design feature of IC1 is that this area of circuitry is completely separated within the silicon chip by a diffusion well and has a separate power supply (VSS').

Protection against overdosing is provided by three basic concepts:

1. Breaking the motor current by the cam-operated microswitch.
2. The complementary, master-slave action of transistors TR1 and TR2.
3. The Guard circuit, with two methods of activation.

Low battery indication

The master-clock in IC1 causes pin 14 to be grounded approximately once per second. During this pulse, transistor TR5 conducts. This illuminates the LED, providing the battery voltage is sufficient to cause about 0.6 volts to be developed across resistor R13.

When the battery voltage is too low to switch on transistor TR5, the LED ceases to flash.

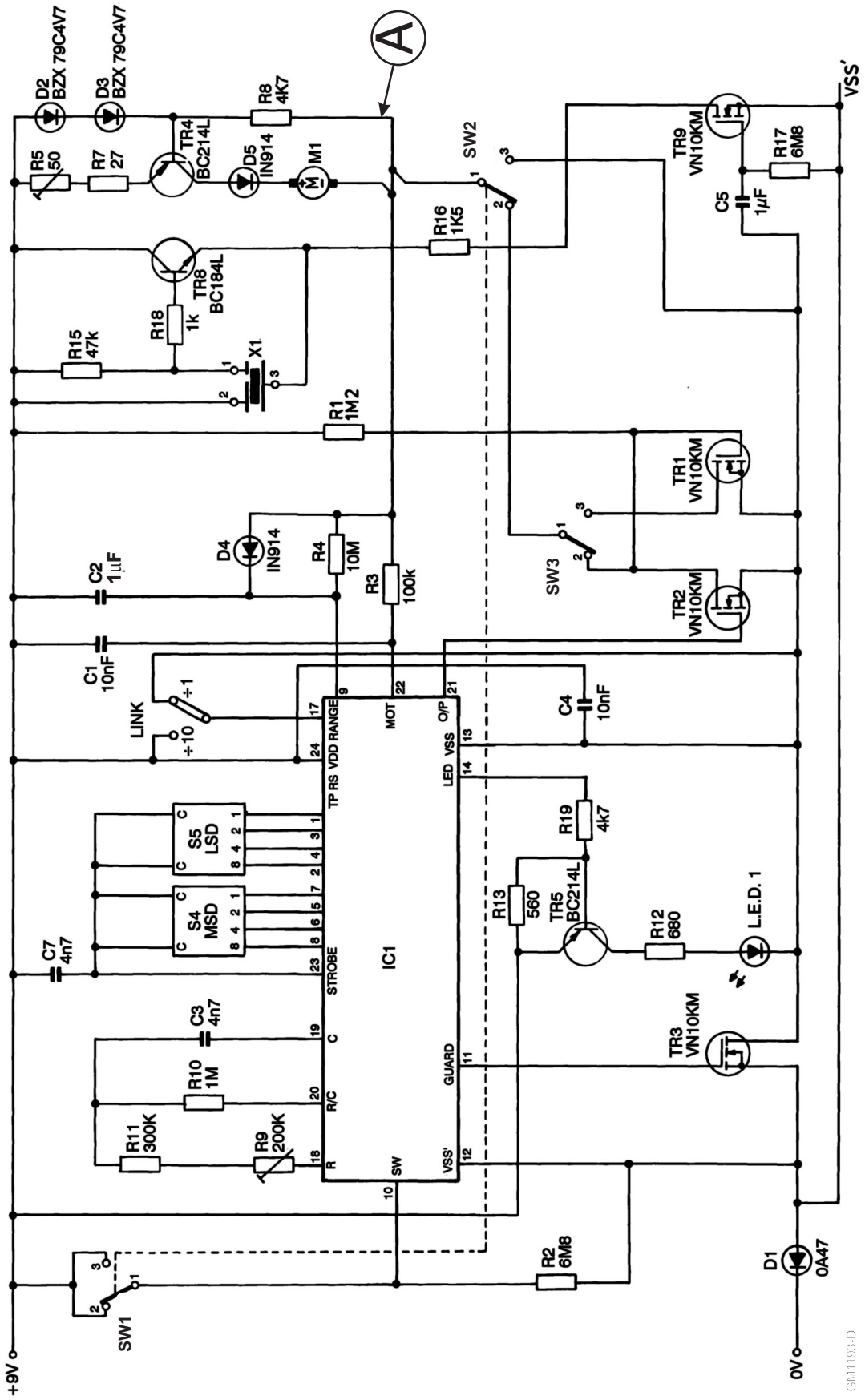


Figure 3-1 MS16A Circuit diagram

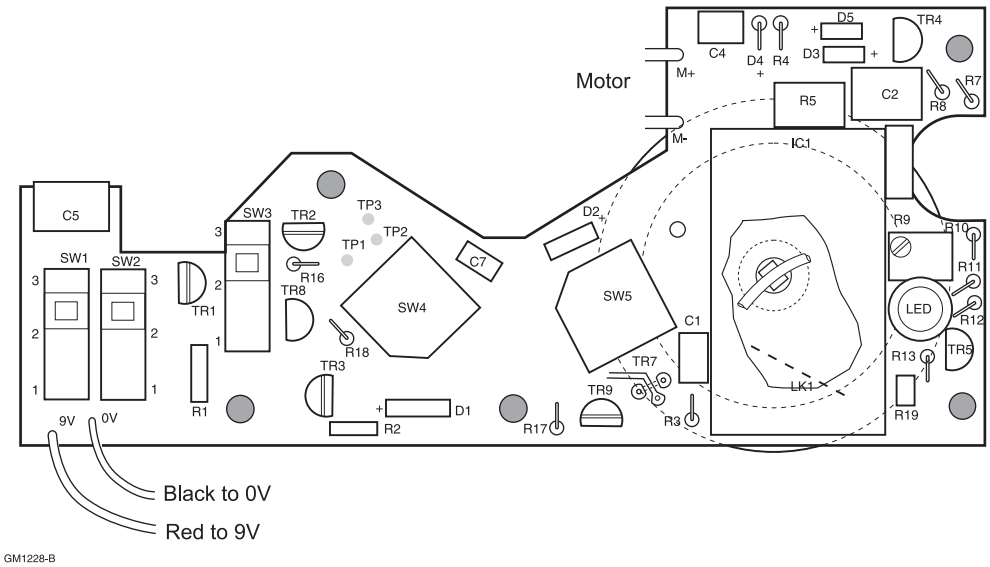
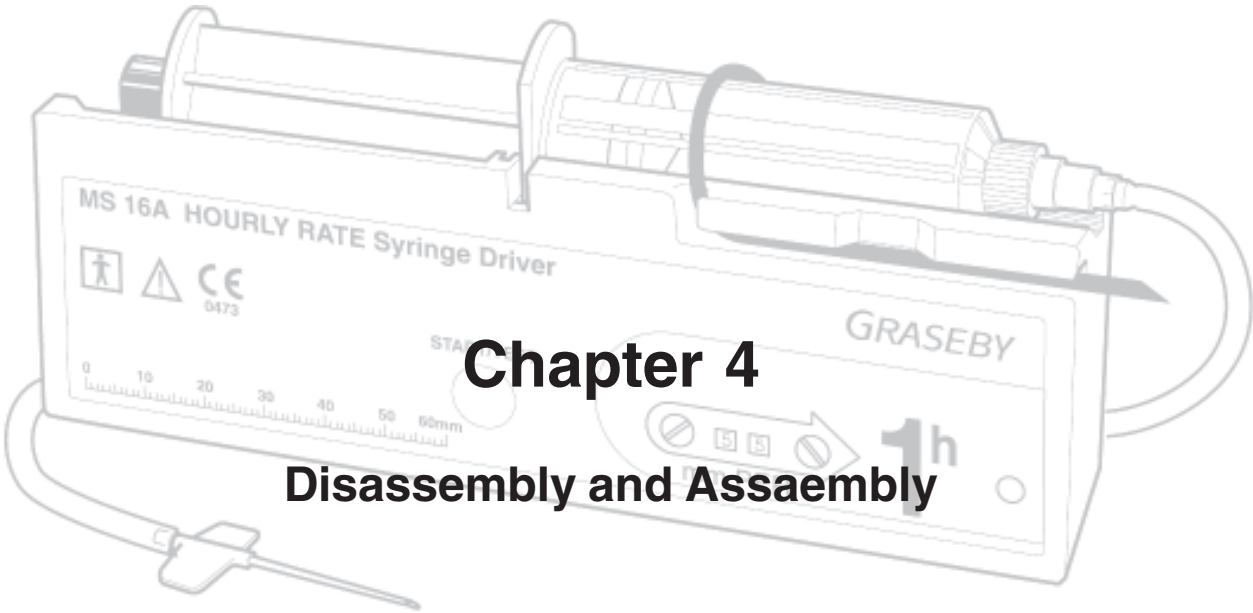


Figure 3-2 MS16A Printed circuit board layout

3

Graseby® MS16A

Syringe Driver



Chapter 4

Disassembly and Assaembly

Chapter 4 - Disassembly and Assembly

General

Warnings:

Refer all service, repair, testing and calibrations only to suitably qualified technical personnel. Unauthorised modifications to the driver must not be carried out.

The use of spare parts other than those recommended is not advised, and may affect the correct operation of the driver, resulting in injury or death.

Cautions:

The moving parts of the driver do not require any lubrication during their lifetime. Any worn or stiff parts should be replaced.

With the case dismantled take great care to avoid contamination of the exposed switches, e.g. by the entry of solder particles.

Handling of printed circuit boards is required during disassembly/ assembly. A static controlled work station including a conductive mat and grounded wrist strap should be used to provide protection against electrostatic discharge (ESD) or circuit board damage could result.

The following procedures describe the dismantling and assembly sequence when replacing parts.

If the case halves are separated, the complete test routine (see *Chapter 5, Testing*) must be completed successfully.

Unless otherwise stated, tighten screws to a torque of 30 - 35 cNm.

A faulty PCB should be replaced with a new PCB.

The item numbers given in the following descriptions refer to *Figure 4-1, MS16A exploded view*.

Tools, equipment and materials required

Cam adjustment tool	*Part number 0105-0079*
Silicone grease	*Part number 6835-2006*

Silicone sealant, non-acetic Loctite 209161, or similar.

For a list of additional tools and materials used when testing the MS16A, see *Chapter 5, Testing, page 5-1.*

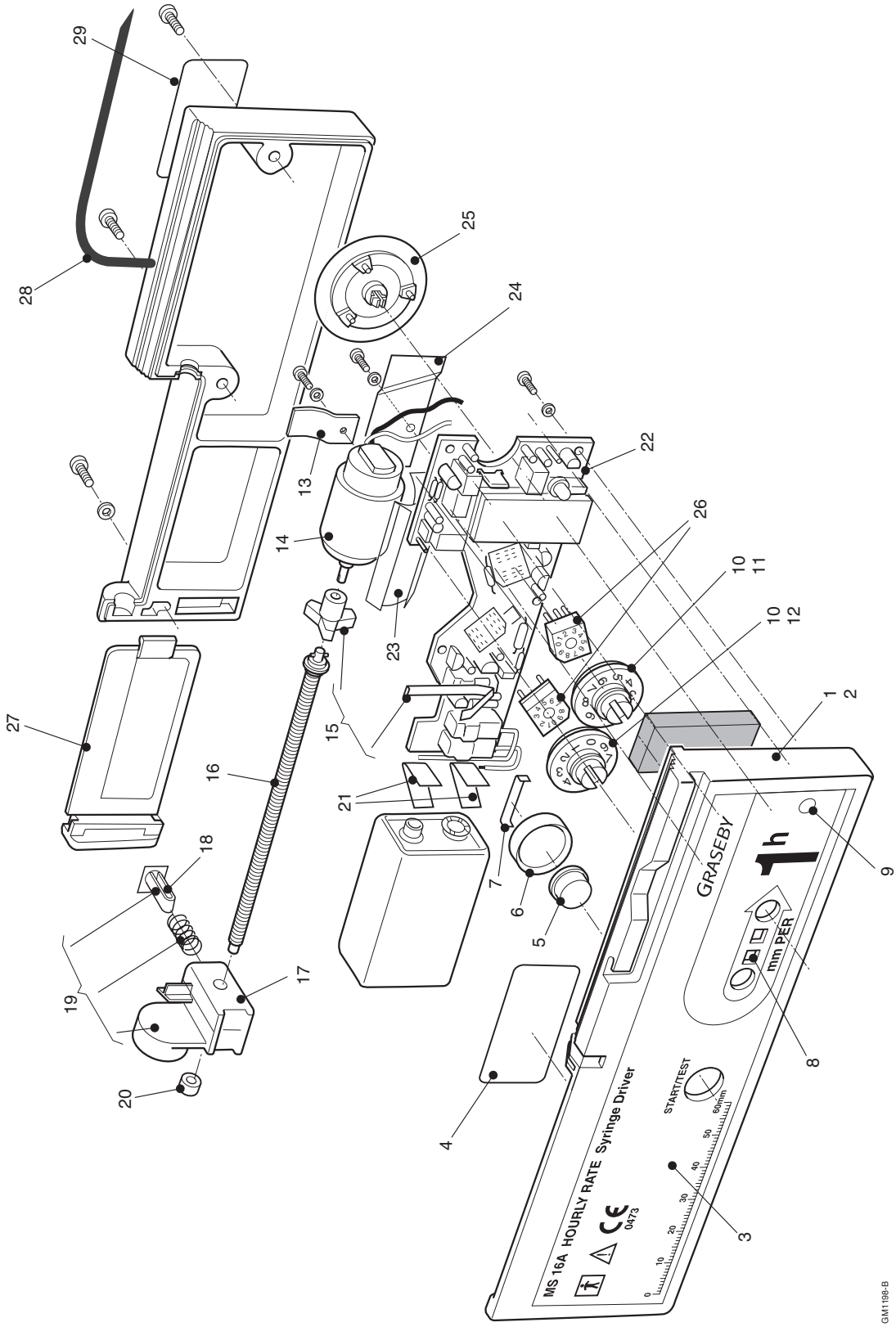


Figure 4-1 MS16A exploded view

Removal and dismantling procedures

1. Case separation

a. Lay the driver face down on a clean flat surface.

b. Slide off the battery cover (item 27) and if fitted, remove the battery.

c. Remove the three screws and washer securing the halves of the case assembly. Lift off the rear half.

d. If the case is sealed, gently pry the two halves apart. Remove any sealant from mating surfaces.

2. Leadscrew and bearing assembly removal

a. Separate the case halves as above.

b. Loosen the motor clamp (item 13) so that the motor and gearbox assembly (item 14) can be tilted clear of the case.

c. Gently pull the leadscrew and actuator assembly (items 15 and 16) from the motor and gearbox assembly.

3. Actuator and back bearing disassembly

a. Separate the case halves and remove the leadscrew and bearing assembly as above.

b. Remove the back bearing (item 20) from the end of the leadscrew.

c. Depress the plunger (half nut - item 18) on the actuator assembly (item 19) and slide the actuator off the leadscrew at the back bearing end.

When the half nut and spring are freed from the leadscrew, ensure that they are not mislaid. Ensure that the half nut is blue-rimmed.

4. PCB removal

a. Separate the case halves and remove the leadscrew and bearing assembly as above.

b. Remove the motor clamp (item 13), screw and fibre washer.

c. Remove the four remaining screws and fibre washers securing the PCB assembly (item 22) to the front case (item 2).

If the wires for the piezo-transducer assembly (item 25) are secured with an adhesive pad to the motor clamp (item 13), carefully lift the leads from the pad.

d. Pull the battery connector springs from their locating slots and lift out the PCB assembly and motor and gearbox assembly.

The **START/TEST** pushbutton, seal and switchplate (items 5, 6 and 7) may remain in the case.

e. To release the piezo-transducer (see *Figure 4-2*) assembly, unplug IC1 from its socket, exposing the fixing clip. Remove the piece of rubber from the clip. Do not pull on the metal disk. Push the clip through, whilst gently holding the transducer assembly.

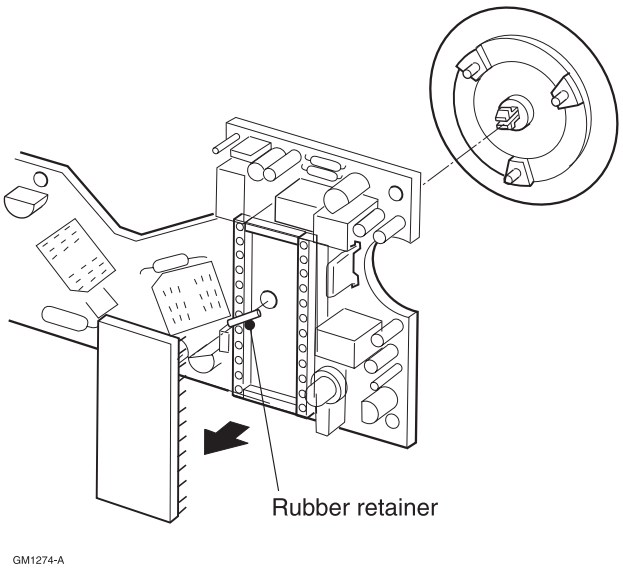


Figure 4-2 Release piezo-transducer assembly

f. To remove the PCB assembly completely, unsolder the motor gearbox assembly (item 14) from the PCB.

g. Ensure that all traces of sealant (if applied) are removed from mating surfaces.

5. Motor and gearbox disassembly

a. Separate the case halves and remove the leadscrew and bearing assembly as described in paragraphs 1, 2 and 3 above.

b. Remove the PCB assembly (see paragraph 4, a - d above).

c. Unsolder the motor and gearbox assembly (item 13) from the PCB.

Assembly procedures

Note: Unless otherwise stated, tighten all screws to a torque of 30 - 35 cNm.

1. Motor and gearbox assembly

a. If a replacement motor is being fitted, align the pin in the cam assembly with the slot in the gearbox shaft and press the cam assembly onto the shaft.

b. Connect and solder the motor leads to the PCB: red to M+ and black to M-.

c. Refit the PCB assembly, complete with the motor and gearbox, and the leadscrew assembly.

2. PCB assembly

Ensure that the transducer is correctly wired to the PCB: blue to TP1, red to TP2, black to TP3.

When reassembled, ensure that the three pegs on the transducer base are located in the holes in the PCB.

a. Fit the two rate dials (items 11 and 12), on the rate switches SW4 and SW5 (items 26). A rubber seal (item 10) must be fitted firmly into the groove, in each of the dials.

i. Place the two dials face-upwards on the bench, side by side, so that the numbers on each dial, on the adjacent sides, are the correct way up (if upside down, change the dials left to right).

ii. Keeping the dials in the same relative position insert the left-hand dial in SW4 and the right-hand dial in SW5, ensuring that the dial position and switch position correspond (see *Figure 4-3*).

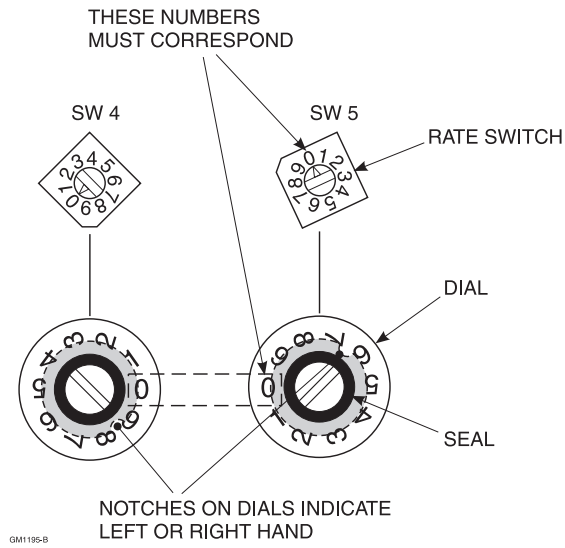


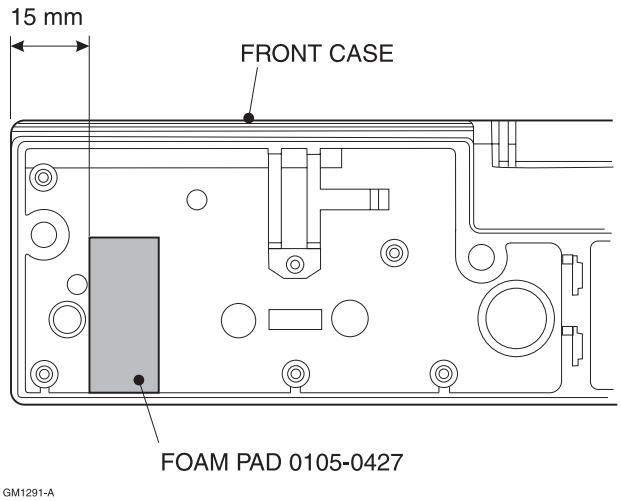
Figure 4-3 Orientation of dials and rate switches

iii. Apply a smear of silicone grease (Smiths Medical *part number 6835-2006*) to the edge of the slotted head screw (items 11 and 12).

b. Assemble the **START/TEST** pushbutton, seal and switch bar (items 5, 6 and 7) and place them in position over microswitches SW1 and SW2.
Ensure that the switch bar is aligned across the contacts of SW1 and SW2.
Ensure that the cam lever (part of item 15) is on SW3 and that it pivots freely.

c. Ensure that the foam pad is fitted to the inside of the front case (see *Figure 4-4, Foam pad position*). Place the front case half (item 1) over the PCB and hold it in position. Turn the PCB and case over so that the PCB is uppermost. Check that the leads for the motor and battery connector springs are not trapped.

Figure 4-4 Foam pad position



d. Push the battery connector springs into their slots. Red to + and Black to - ve, as shown on the battery compartment label.

e. Secure the PCB in position with five screws and fibre washers. The switch pin insulator (item 24) must be held by the lower middle screw and separate the PCB from the piezo-transducer.

f. Check for correct operation of the **START/TEST** pushbutton and that clockwise rotation of both rate switches causes the dials to indicate increasing numbers.

g. Place the motor and gearbox in position and fit the insulating spacer (item 23). Fit the motor clamp (item 13) with the securing screw and washer; do *not* tighten the screw.

Note: The motor case has two pegs on the front face, align the motor so that the pegs do not foul the locating pillar in the case assembly.

h. Assemble the actuator and back bearing and the leadscrew and bearing.

3. Actuator and bearing

a. Ensure that the motor clamp (item 13) is loose.

b. Depress the plunger into the half nut and slide the actuator assembly onto the leadscrew from the back bearing end. *Figure 4-1* shows the correct way the actuator (item 18) faces.

c. Fit the back bearing to the end of the leadscrew.

d. Assemble the leadscrew and bearing assembly.

4. Leadscrew and bearing assembly

a. Align the pin on the leadscrew and bearing assembly with the slot in the cam assembly and press the leadscrew into position.

b. Ensure that both front and back bearings fit snugly in their recess in the case assembly.

c. Check the motor is still correctly positioned (see *Figure 4-5)*. Use a fresh adhesive pad on the clamp to hold the wires.

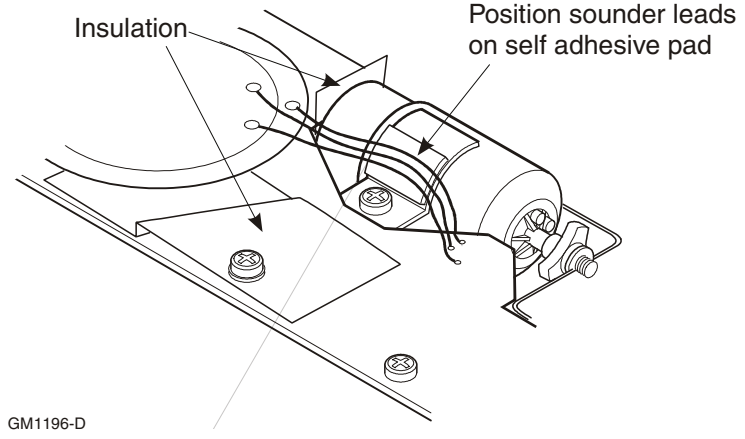


Figure 4-5 Piezo-transducer wiring

d. Tighten the clamp screw.

e. Assemble the case.

5. Case assembly

Before the case is re-sealed:

- ensure that *all* internal work is complete,
- seal the case halves using a non-acetic silicone sealant (e.g. Loctite part number 6815-1544), and
- follow all instructions supplied with the sealant, observing recommended practices.

Do not use domestic silicone sealants.

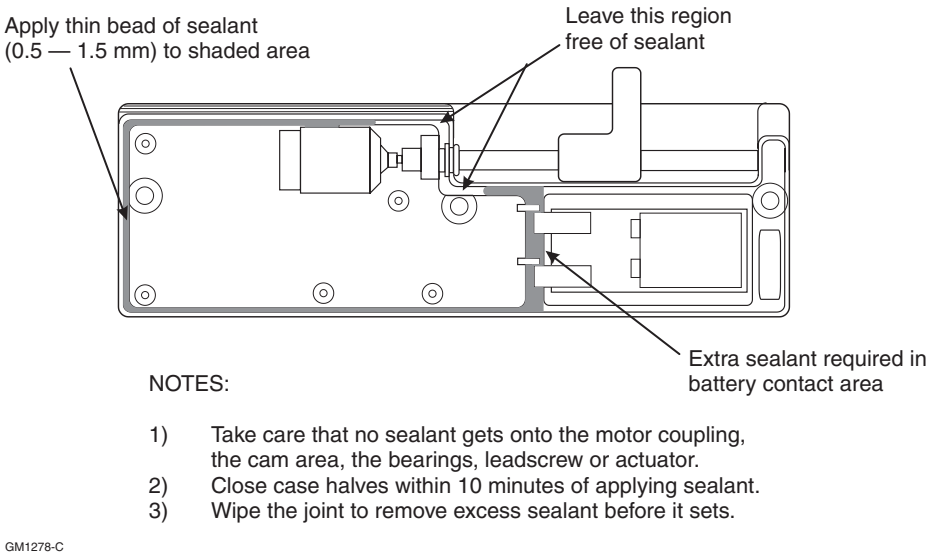

Apply thin bead of sealant
(0.5 — 1.5 mm) to shaded area
Leave this region
free of sealant
Extra sealant required in
battery contact area
NOTES:
1) Take care that no sealant gets onto the motor coupling, the cam area, the bearings, leadscrew or actuator.
2) Close case halves within 10 minutes of applying sealant.
3) Wipe the joint to remove excess sealant before it sets.
GM1278-C

Figure 4-6 Sealant application

a. Ensure that alternate motor pulses do not differ by more than 20%. See *Chapter 5, Testing - Cam Adjustment.*

b. Ensure that all traces of original sealant are removed.

c. Check that mating faces are clean and dry using an isopropyl alcohol cleaner.

d. Apply a continuous thin bead around the inner lip of the front case half as shown in *Figure 4-6.*

Keep the area around the cam and bearing free of sealant.

Note: Close the case halves within 10 minutes of applying the sealant.

e) Position the rear case half, checking that the piezo-transducer disc is centrally placed on the black clip. Secure the case with three screws. Ensure that a washer is fitted with the screw beneath the battery cover.

f. Clean off any excess sealant before it sets. The setting time is as specified for the sealant selected.

Note: Ensure that the serial number label (item 4) is fitted and complete.

g. Fit the battery, observing the correct polarity as shown by the illustration in the battery compartment.

The alarm sounds for about 15 seconds. If this does not happen, fit a new battery.

h. Refit the battery compartment cover.

j. Complete tests specified in Chapter 5, *Testing*.

Lockbox

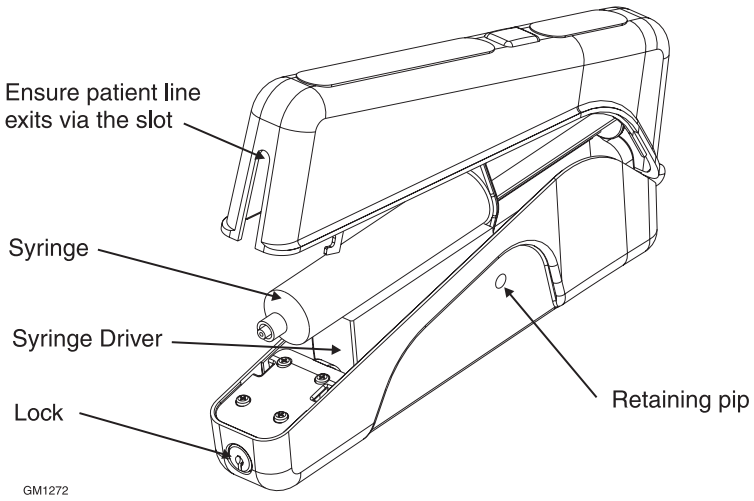


Figure 4-7 Lockbox

Installation

To install the syringe driver in the lockbox:

1. Unlock and open the box.
2. Place the syringe driver in the box (**mm PER** arrow pointing to the lock).
3. Ensure the retaining pip clicks into the recess on the driver.
4. Close and lock the lid, ensuring that the patient line exits via the slot above the key.

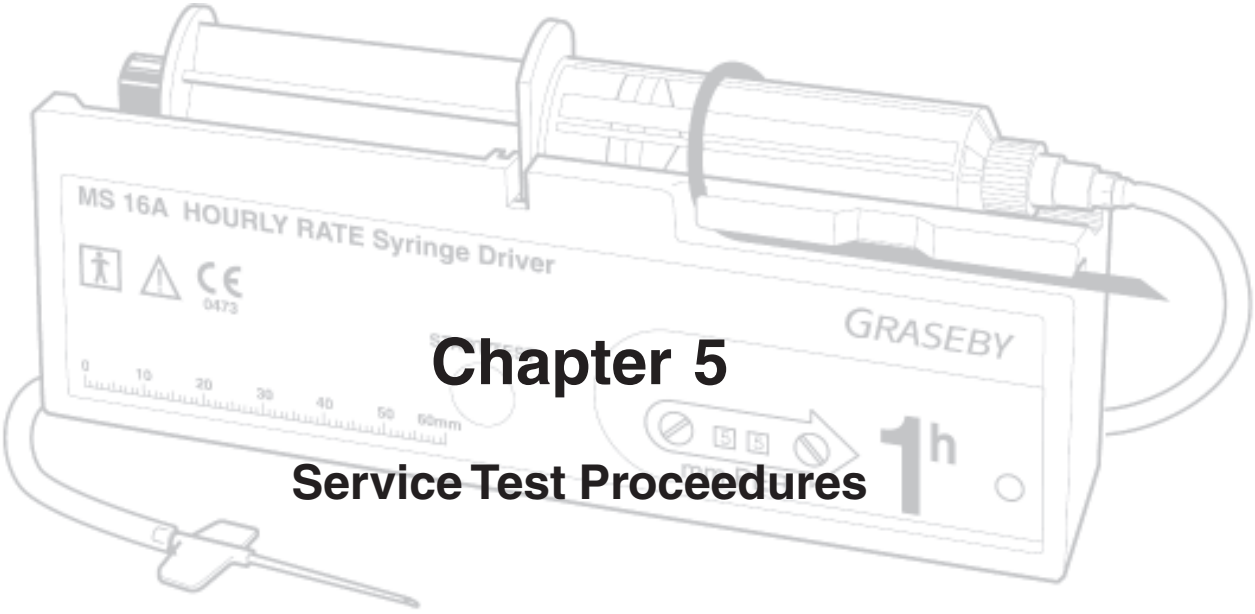
CAUTION Always ensure that the tubing is not kinked or trapped.

Removal

To remove the driver from the lockbox, unlock the box and open the lid. Ease the retaining pip from the side of the driver and remove the driver.

Graseby® MS16A

Syringe Driver



Chapter 5

Service Test Proceedures

Chapter 5 - Service Test Procedures

This chapter describes the functional testing of the Syringe Driver. The routines must be followed whenever the case is opened, components replaced or any repair completed

Typical situations include:-

- routine planned preventative maintenance (PPM),
- after the pump has been opened *whether or not repaired*,
- whenever it is required to verify that the pump is safe to use.

Note: The case must be resealed if the case halves have been separated.

Smiths Medical recommends that the Syringe Drivers are functionally and safety tested annually, particularly if they've been accidently maltreated.

Although the case is sealed, it is not intended to be fully waterproof. It is merely a matter of good practice to check the functionality of a unit before using it in a patient-critical situation.

Tools and equipment

The following tools and equipment are required to complete the adjustments, tests and calibrations:

Description	Part number
Cam adjustment tool	0105-0079
Thrust rig	0105-0651
Spring test gauge assembly or weights: 1.5 kg, 2 kg, 3 x 5 kg	0105-0083
Stop watch - 1/2 sec resolution	
Linear Accuracy Rig	0105-0858
Vernier calipers	
0 - 10 V variable DC supply at up to 50 mA.	
*Dummy rear case (refer to Smiths Medical Service Dept.)	
Standard Service Department tools and equipment.	

* A dummy rear case consists of a rear case that has been cut in half so that only the battery end of the case (with two fixing holes) remains.

Adjustment potentiometers

The adjustment potentiometers VR5 and VR9 are behind the front panel label.

Peel back the front panel label from the righthand side (nearest the LED) to expose the access holes to the resistors.
Variable resistor VR9 (thrust) is located directly above the LED.
VR5 is near the top.

When adjustments have been completed, it may be necessary to replace the front panel label if it does not adhere when pressed back in position.

When replacing the label, ensure that the small clear plastic window is in its recess over the rate dials.

Notes: If any unit is found to be over or under infusing during testing, inform your local RAQA Department.

Ensure that the button surround on the actuator body is blue (*Figure 7-1, items 15 and 14*)

Service Testing:

Note: Before starting, separate the cases and fit a dummy rear case. Connect a link from TP2, behind the lefthand square window, to +9 V and another link from TP1, behind the righthand square window to 0 V.

1. Cam follower adjustment

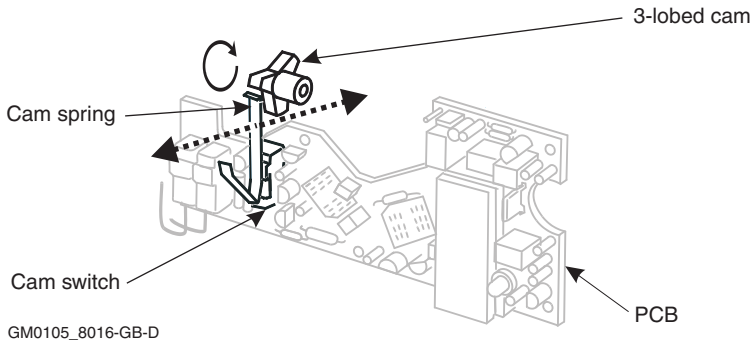


Figure 5-1 Cam and cam follower

The cam switch makes six transitions (ON > OFF or OFF > ON) every revolution. Each transition causes the motor current to be cut off. Pulses 1, 3, and 5 will be terminated by the microswitch MAKING, and pulses 2, 4, and 6 will be terminated by the microswitch BREAKING the circuit. The motor must be restarted with a fresh command to continue, making the system inherently safe in operation.

Pulses 1, 3, and 5 are likely to be very similar to each other (as are pulses 2, 4, and 6). If wear or damage has occurred, the duration of the odd pulses may significantly differ from the duration of the even pulses. Alternate motor pulses are permitted to be of slightly different lengths but should not differ by more than 20%.

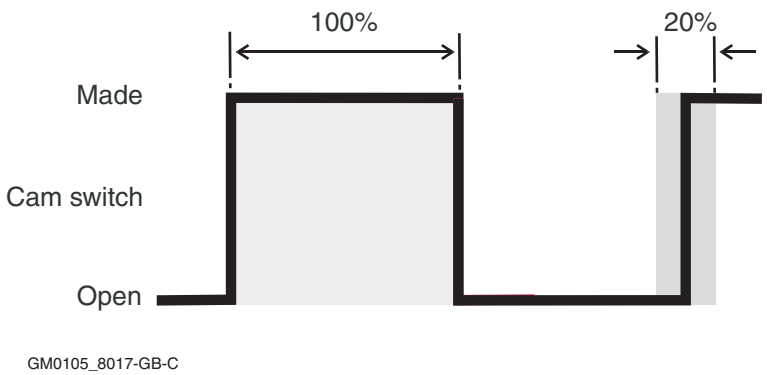


Figure 5-2 Camswitch operating timing

To measure the motor interval time, a conventional scope with a good trigger is required; a storage scope would be better. Using the variable power supply, place a 4R7 ohm resistor in the negative supply line, and with a x10 scope probe, measure the voltage across the resistor.

Run the pump at maximum rate and compare each consecutive pulse over six pulses. *Figure 5-3* illustrates the typical waveform expected. The motor run time is measured from the start of the plateau to the trailing edge of the waveform, where it is cut off by the cam's action.

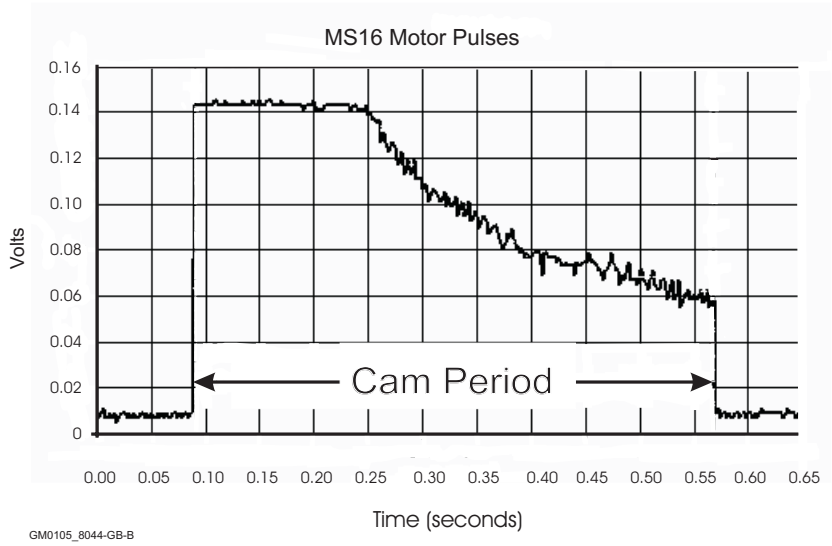


Figure 5-3 Typical waveform for one pulse

The variation in duration of the six consecutive pulses in each revolution should not be more than 20%. If necessary, adjust the motor run-time ratio by a slight bending of the cam follower lever, using tool *part number 0105-0079*. Use the tool as shown in *Figure 5-4* to tweak the operating lever so as to mimimise the error.

Note that the time interval between successive pulses may vary slightly. This is not a controlled parameter, and variation is permitted.

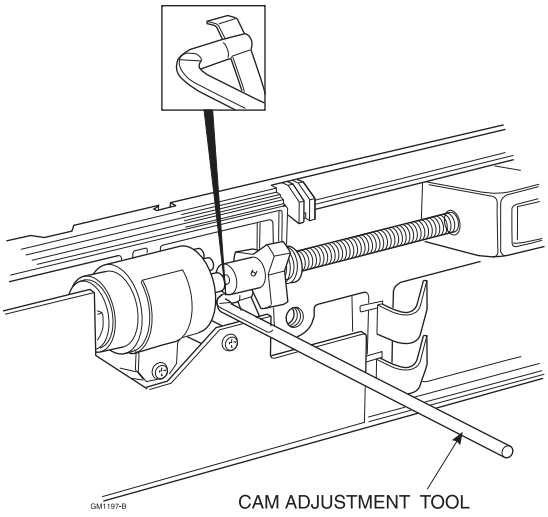


Figure 5-4 Using the cam adjustment tool

2. 9 Volt thrust test

a. Fit the dummy case to the driver.

b. Ensure that the battery and battery cover are removed.

c. Load the unit onto the Thrust rig as shown in *Figure 5-5 Thrust rig set-up*. Set the actuator 50 mm from end of travel.

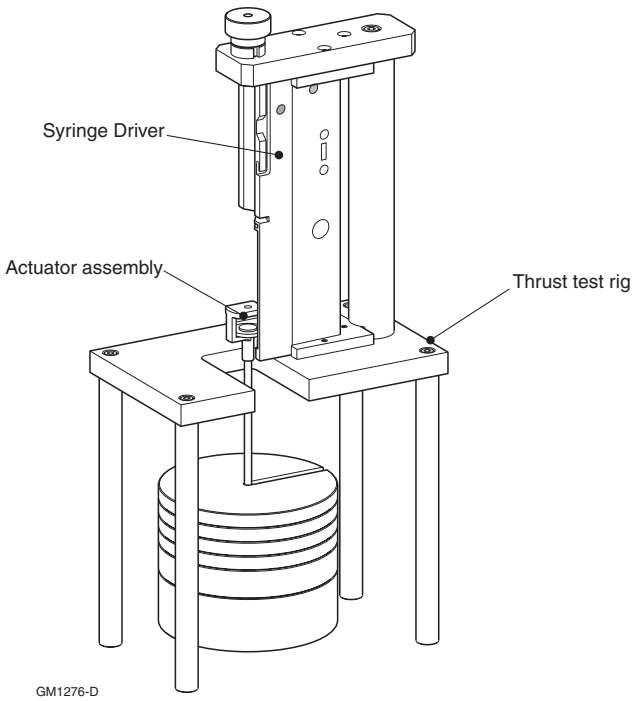


Figure 5-5 Thrust rig set-up

d. Connect to the syringe driver a 9 V DC power supply.

e. Set the rate dials to read 99.

f. Start the syringe driver.

g. Load the actuator with a weight of 4.5 kg. Reduce VR5 until the driver starts to stall.

h. Reduce the load to 4 Kg. Allow the driver to run for a minimum of six motor pulses and then replace the 1/2 Kg weight. The driver must stall at 4.5 Kg within 6 motor pulses. If it will not stall, repeat step (e).

3. 7 Volt thrust test

a. Reduce the power supply to 7 V DC and set the actuator 10 mm from the end of travel.

b. Start the syringe driver running and allow two motor pulses. Load the actuator with a 3 Kg load. The unit must run for six or more motor pulses without stalling

c. Reset the power supply to 9 V DC.

d. Remove the driver from the Thrust rig.

4. Guard test

a. Temporarily short pin 20 (IC1) to + rail. Hold down the **START/TEST** pushbutton and check that the motor starts and then stops in 5 - 10 seconds.

b. Remove the short from pin 20.

5. Flash frequency

a. Set rate to 00 mm/hr, start normal running and monitor the front-panel LED flash period.

b. The period between flashes should be 1.029 seconds (minimum) - 1.071 seconds (maximum), i.e. 1.050 seconds ± 2%. Adjust R9 if necessary.

c. Alternatively, if using a timer/ counter, the flash frequency should be set at between 0.97143 Hz (max) and 0.93333 Hz (min).

d. The flash frequency should not change by more than 1.5% when the supply voltage is reduced to 7 volts.

6. Timer and feed rate tests

Place the syringe driver in the Linear Accuracy Rig, *part number 0105-0858*, place the dti extension rod on the actuator assembly and set the dti to zero.

a. With a supply of 9 volts, set the rate to 55 and check that the time for 5 motor pulses to occur is 36 - 41 secs. Ensure that the actuator advances along the leadscrew a distance of 0.55 - 0.61 mm in this time.

b. Set the rate to 66 and check that the time for 5 motor pulses to occur is 30 - 33.5 secs.

c. Set the rate to 99 and check that the time for 10 motor pulses to occur is 40 - 45 secs. Hold down the **START/TEST** pushbutton and check that the motor starts and then stops and sounder cuts in between 3.3 - 4.0 secs.

d. Release the **START/TEST** pushbutton. Observe that the unit restarts, with flashing LED and a single motor pulse.

7. Cam alignment

Increase power supply to 10 V DC and check that six pulses equals one revolution of the leadscrew.

8. Half nut slip

Set the supply at 10 V DC and rate at 99. Check for correct stalling. The LED must stop flashing, the alarm must sound, and the half nut must *not* slip, when the actuator runs to the end of the leadscrew. Repeat at least twice.

9. Rate switch test

a. Set rate to 36 and check that the time for 10 motor pulses to occur is 11 - 13 secs.

b. Set rate to 00 and start the driver (LED flashing). Check that no motor pulses occur over a period of at least 8 minutes. This can be most easily determined by an absence of actuator movement.

The syringe driver may be removed from the Linear Accuracy Rig before continuing.

10. Current tests

a. At a supply voltage of 9 V DC, measure the supply current with the unit in the OFF state (LED not flashing, alarm silent). Check this does not exceed 5 mA.

b. Set rate to 00 and start unit (LED flashing). Check that the supply current (excluding LED flashes) does not exceed 50 mA at any time in a 30 second test period.

11. Sounder check

Check that whenever power is restored (e.g. battery removed and replaced), an undistorted sound, clearly audible at arms length and lasting 5 - 20 seconds, is produced.

12. General

a. Check that both case halves are in good condition and that all interior screws are present and tightened.

b. Remove the dummy case and fit the rear case (see *Chapter 4, Case assembly*).

c. Affix new front label if required and seal unit.

d. Clean the unit and fix the appropriate Service Label.

e. Ensure that the History record sheet is completed.

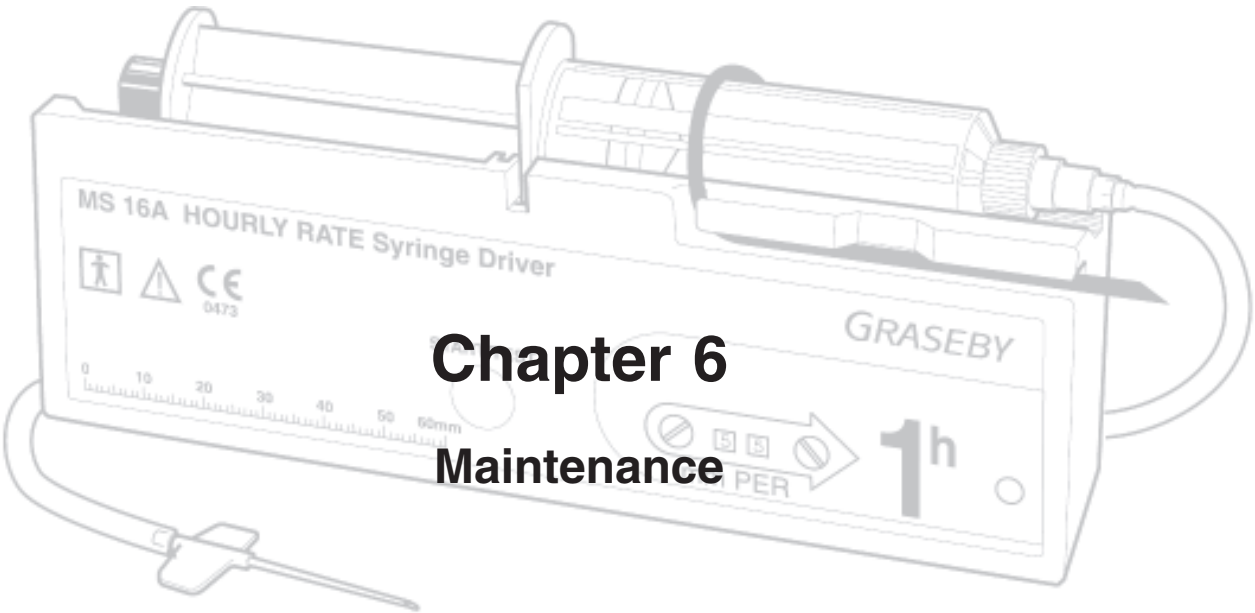
Test Checklist - MS16A

Tester: . . . . . .

Syringe driver serial no. . . . . . **Date:** . . . . . .

Test	Action	Pass/Fail	Comment
1	Cam follower adjustment		Even (± 20%) pulses
	Actuator plunger check?		Is it blue?
2	9 volt thrust test		4.5 kg max.
3	7 volt thrust test.		3.0 kg min.
4	Guard test.		Motor stops within 10 secs.
5(b)	Flash frequency / period at 9 Volt supply		20 flashes in 20.5 - 21.5 secs. *or* 1.05 ± 2% sec per flash *or* 0.93333 - 0.97143 Hz.
5(d)	Flash frequency / period at 7 Volt supply		Change less than 1.5%
6(a)	Set rate switches to 55, time 5 motor pulses.		Min 36 secs, max 41 secs. Actuator should travel 0.55 - 0.61 mm.
6(b)	Set rate switches to 66, time 5 motor pulses.		Min. 30 secs, max 33.5 secs.
6(c)	Set rate switches to 99, time 10 motor pulses.		Min. 40 secs, max. 45 secs.
6(d)	Hold START/TEST should run 3 - 4 secs. then cut out.		Sounder sounds for few seconds after motor stop. Behaviour can be repeated.
6(e)	Release pushbutton.		Unit restarts and runs normally.
7	Cam alignment.		1 rev. for every 6 pulses.
8	Half nut slip.		Alarm sounds and driver shuts off at end of travel without slip. Do twice.
9(a)	Set rate switches to 36, time 10 motor pulses.		Min. 11 secs, max. 13 secs.
9(b)	Set rate switches to 00, check actuator.		Should be stationary for 8 minutes or more.
10(a)	Quiescent current (off).		< 5 mA.
10(b)	Current (on but stationary).		< 50 mA.
11	Sounder check.		Clearly audible on battery insertion.
12	General check.		Case in good condition. All labels properly present. Case sealed.

Graseby® MS16A
Syringe Driver



Chapter 6

Maintenance

Chapter 6 - Maintenance

Caution: Handling of printed circuit boards is required during disassembly/ assembly. A static controlled work station including a conductive mat and grounded wrist strap should be used to provide protection against electrostatic discharge (ESD) or circuit board damage could result.

Maintenance

The Department of Health, in its publication MDA DB 9503, has recommended that infusion drivers are checked by a qualified technician at regular intervals.

Smiths Medical supports this policy, and recommends that the tests and if necessary the adjustments given in Chapters 5 and 6 of this publication should be carried out at regular intervals.

Additionally, with reference to the Department of Health publication 'SAB(94)26 July 1994', we recommend that for any of our products that have been dropped or subjected to severe fluid spills, should be removed from use immediately, and be checked by a qualified technician.

Cleaning

Warnings: To prevent serious damage to the driver it must *not* be immersed in any liquids or exposed to strong organic solvents.

Wipe off spills immediately. Do *not* allow fluids or residues to remain on the pump.

The pump is *not* designed to be sterilised.

Failure to observe these warnings may cause internal damage to the pump resulting in patient injury or death.

To clean the driver, wipe the case with a damp cloth (soapy if necessary). Allow the driver to thoroughly dry before use.

To reduce wear on the actuator assembly, clean the leadscrew using a small brush with stiff bristles, e.g. a tooth-brush.

Annual performance check

Check the performance of the driver annually following the tests shown in *Chapter 5, Testing*.

Battery replacement

The unit uses an IEC 6LR61 battery (9 V, alkaline, PP3 size), e.g. DURACELL MN1604.

The use of rechargeble cells are **not** recommended.

Some Duracell type batteries do not fit snugly in the battery conmpartment. The metal can on the battery catches and deforms at th rear of the compartment.

A new battery must be fitted when the indicator lamp fails to flash.

1. Remove the driver from the lockbox (if fitted). See *Chapter 4, Disassembly and Assembly*.
2. Slide off the battery compartment cover at the back of the driver.

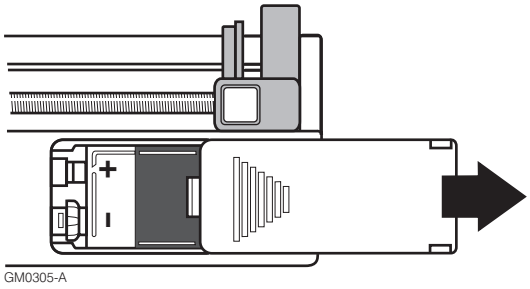


Figure 6-1 Battery replacement

3. Turn the driver upside down and carefully remove and discard the battery (ensure that national or local regulations concerning battery disposal are followed.
4. Insert a new battery into the battery compartment, ensuring correct polarity as shown by the illustration in the battery compartment.

Notes: The driver is protected against the effects of accidental reverse polarity of the battery.

The alarm sounds for about 15 seconds after the battery is fitted.

If fitting the battery is difficult, insert the rear of the battery first and then push the terminal end down.

If the fit is still tight, source an alternative brand of 6LR61 alkaline battery.

6. Fit the battery compartment cover, ensuring that it snaps into place when closed
7. Place the driver in the lockbox (if fitted). See *Chapter 4, Disassembly and Assembly*.

Continuous alarm conversion

If required, the alarm may set to a continuous tone when the syringe stops e.g. at the end of an infusion.

To change the alarm tone:

1. Separate the case halves and remove the leadscrew and bearing assembly (see *Chapter 4, Disassembly and Assembly*).
2. Remove one screw, one fibre washer and the motor clamp (see *Figure 4-1*).
3. Remove the remaining four screws and fibre washers securing the PCB assembly to the front case.

   If the wires for the piezo-transducer assembly are secured with an adhesive pad to the motor clamp, carefully lift the leads from the pad.
4. Pull the battery connector springs from their locating slots and lift out the PCB assembly complete with microswitches and motor and gearbox assembly.

   The **START/TEST** pushbutton, seal and switchplate may remain in the case.
5. Remove the PCB completely.
6. Remove capacitor C5 and resistor R17 from the board.

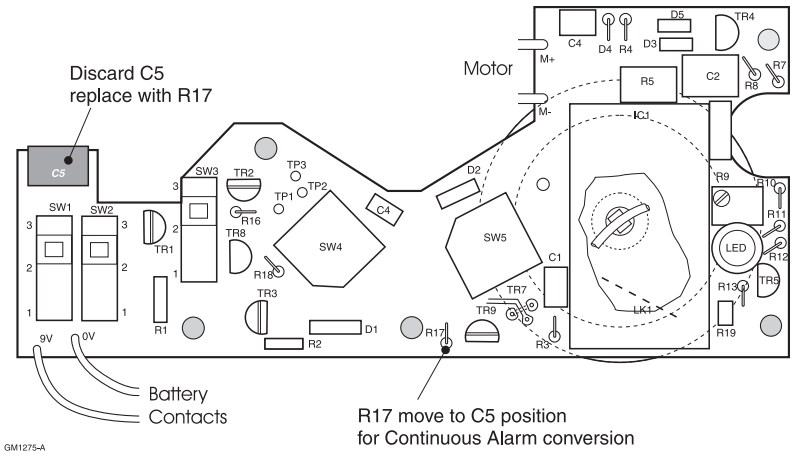


Figure 6-2 Continuous alarm conversion

7. Fit resistor R17 in the C5 position.
8. Assemble the driver (see *Chapter 4, Disassembly and Assembly*).
9. Test the driver (see *Chapter 5, Testing*).

   Ensure that the alarm tone is continuous when the motor stops.
10. Check that the alarm stops when an infusion starts (and when the battery is removed.

Basic Troubleshooting

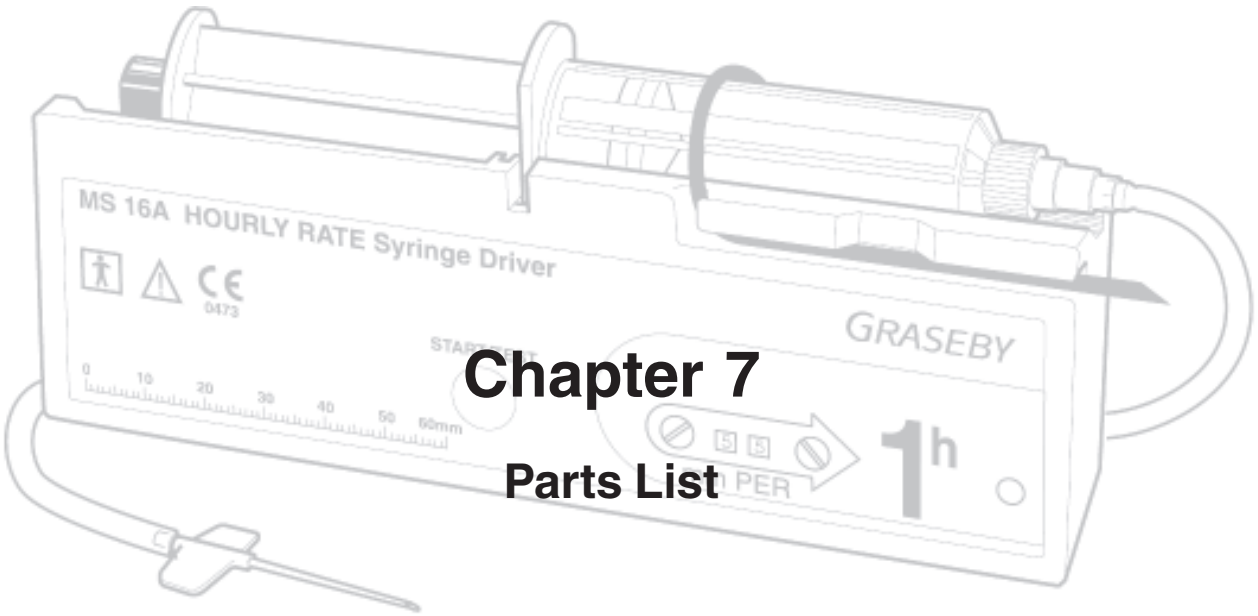
Basic troubleshooting information on the syringe driver is also given in the Instruction Manual, *part number 0105-0549*.

Fault	Possible cause	Action
The Syringe Driver will not start.	The **START/TEST** pushbutton not pressed in enough. Flat battery. There is no battery. The battery is the wrong way round. The rubber insulator cap is still on the terminal. The Syringe Driver is faulty.	Press in correctly. Fit a new battery. Fit a battery. Fit battery correctly as shown on the diagram in the battery compartment.
The infusion is going too quickly or has ended early.	Wrong rate set. Syringe plunger pushbutton or finger grips not held in the actuator or case correctly. Plunger position measured wrongly. Line was filled after the plunger position was measured. Rate set for MS26 on the MS16A. Syringe driver has become wet.	Correct error. Correct error. Correct error. Correct error. Correct error. Recalculate rate for MS16A. Remove from use and disassemble, clean, reassemble, seal and test.
The infusion runs slow.	Wrong rate set. Wrong syringe brand or size. Plunger position measured wrongly.	Correct error. Correct error. Correct error.
Syringe Driver stops before emptying the syringe.	Exhausted battery. Blocked or trapped infusion line.	Fit new battery. Clear line.
Syringe Driver stops with LED still flashing.	Driver mechanism worn. The motor may click.	Technician to replace worn component(s).

Note: Ensure that the new-style label, a blue half-nut and the latest actuator are fitted.

Graseby® MS16A

Syringe Driver



Chapter 7

Parts List

Chapter 7 - Parts List

General assembly of the MS16A

Item No.	Description	Part Number
1	Case complete, consisting of:-	0105-0517
	Front body assembly, Rear body assembly, Battery cover, rate dial window, Non CE marked front panel label (English), spacer insulating, Insulator (switch pin), Instruction label.	
2	Front body sub-assembly (including Foam Pad)	0105-0558
	Foam Pad	0105-0427
3	Front Panel label	
IMPORTANT:	**When ordering a CE marked Front Label, please supply the serial number details of the Syringe Driver, if this information is not supplied then a Non CE marked label will be issued. It is the responsibility of the owner to ensure that the correct labels are replaced on the Syringe Driver.**	
	Non CE marked - English	0105-0023
	Non CE marked ***MS16 only*** - English	0105-0118
	Non CE marked - French	0105-0109
	Non CE marked - German	0105-0119
	Non CE marked - Dutch	0105-0578
	Non CE marked - Italian	0105-0581
	CE marked - English	0105-0563
	CE marked - Spanish	0105-0565
	CE marked - German	0105-0572
	CE marked - French	0105-0574
	CE marked - Dutch	0105-0579
	CE marked - Italian	0105-0580
	CE marked - Danish	0105-0588
	CE marked - Swedish	0105-0593
	CE marked - Greek	0105-0605
	CE marked - USA (Marcal)	0105-0626
4	S / N label non-USA “Made in UK”	0105-0534
	S / N label USA (Marcal)	0105-0617
5	Pushbutton	0105-0009

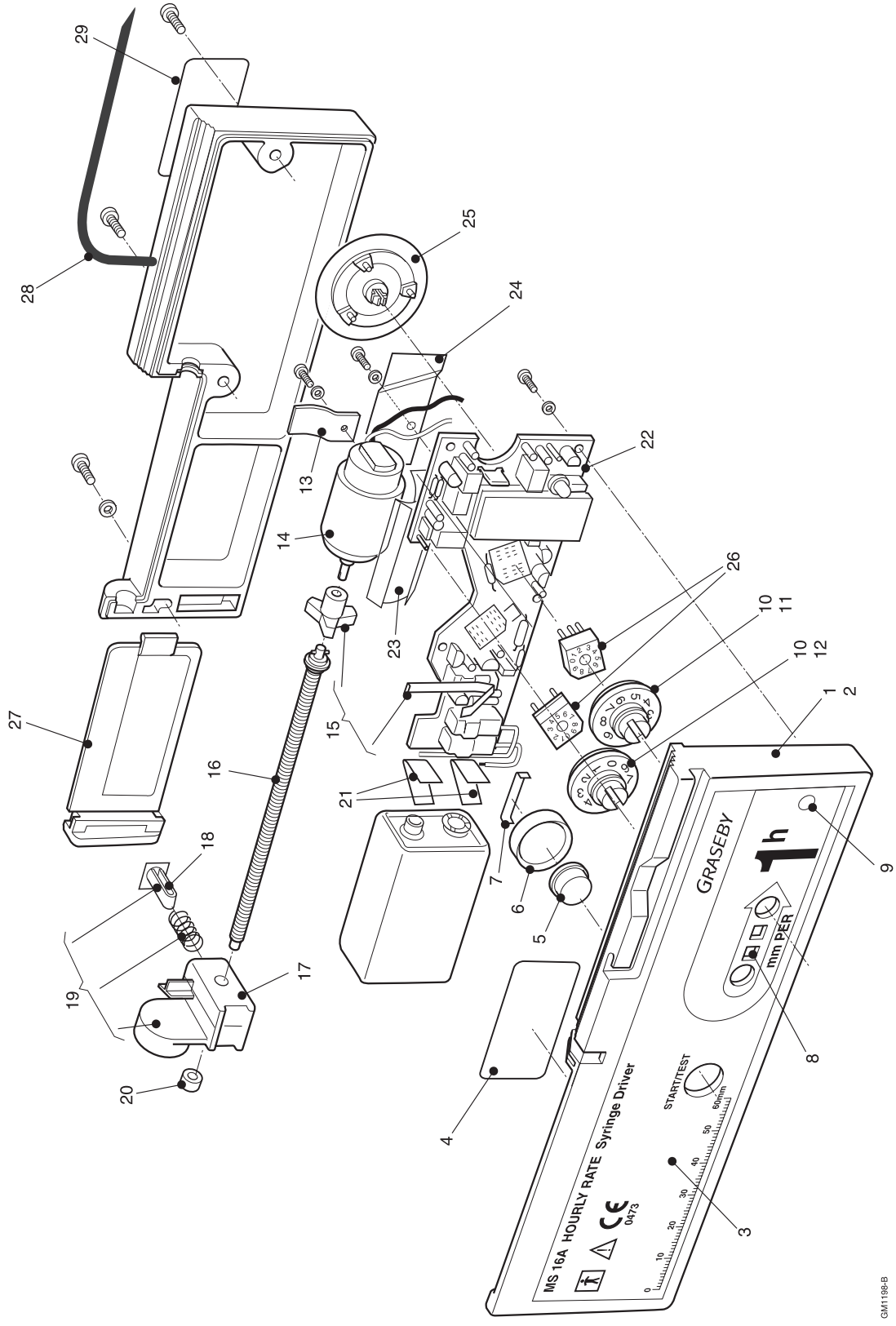


Figure 7-1 Exploded view of the MS16A Syringe Driver

General assembly of the MS16A (continued)

Item No.	Description	Part Number
6	Button seal	0105-0032
7	Switch bar	0105-0060
8	Rate dial window	0105-0035
9	LED window	0105-0074
10	Rate dial seal	0105-0016
11	Rate dial right	0105-0429
12	Rate dial left	0105-0430
13	Motor clamp	0105-0019
14	Motor and gearbox assembly	0105-0059
15	Switch lever and cam kit	0105-0432
	consists of the following parts:	
	Cam and pin assembly, Camspring	
16	Leadscrew and bearing assembly	0105-0031
17	Actuator body	0105-0116
18	Blue Half nut / Button assembly	0105-0801
19	Actuator assembly	0105-0041
	consists of the following parts:	
	Blue Half nut / Button, Actuator body, Actuator spring	
20	End / back bearing	0105-0011
21	Battery contact	0105-0069
22	PCB assembly	0105-0503
23	Spacer insulating	0105-0520
24	Switch pin insulator	0105-0542
25	Piezo-transducer assembly (x 1)	0113-0017
26	Rate switch	3571-0000
27	Battery cover	0105-0006
28	Securing strap	0105-0040

General assembly of the MS16A (continued)

Item No.	Description	Part Number	
29	Instruction label - GMI	0105-0552	
	Instruction label - Spanish	0105-0566	
	Instruction label - English	0105-0571	
	Instruction label - German	0105-0573	
	Instruction label - French	0105-0575	
	Instruction label - Dutch	0105-0577	
	Instruction label - Italian	0105-0582	
	Instruction label - Danish	0105-0589	
	Instruction label - Swedish	0105-0594	
	Instruction label - Greek	0105-0606	
	Tracking label - (Marcal) “Made in UK”	0105-0627	
30	Instruction manual		Not illustrated
	English	0105-0549	
	GMI (USA)	0105-0550	
	German	0105-0559	
	French	0105-0560	
	Italian	0105-0562	
	Spanish	0105-0564	
	Dutch	0105-0576	
	Danish	0105-0587	
	Swedish	0105-0592	
	Greek	0105-0604	
	Marcal “Made in UK”	0105-0629	
31	Carrying case	0000-0001	Not illustrated
32	Syringe cover	0105-0529	Not illustrated
33	Syringe driver base	0105-0108	Not illustrated
34	Fabric holster	0105-0027	Not illustrated
35	Training dummy	0105-0707	Not illustrated
36	Rate adjuster and key ring measuring tool	0105-0623	Not illustrated
37	Rate adjusting key	0113-0023	Not illustrated

38	Service manual	00SM-0105	Not illustrated
39	Cam adjusting tool	0105-0079	Not illustrated
40	Spring test gauge assembly	0105-0083	Not illustrated
41	Lockbox	0105-0640	Not illustrated
42	Spare Key Kit	0151-0641	Not illustrated
43	Battery Cover Label (Marcal)	0105-0616	Not illustrated
44	Linear Accuracy Rig	0105-0858	Not illustrated

MS16A PCB assembly

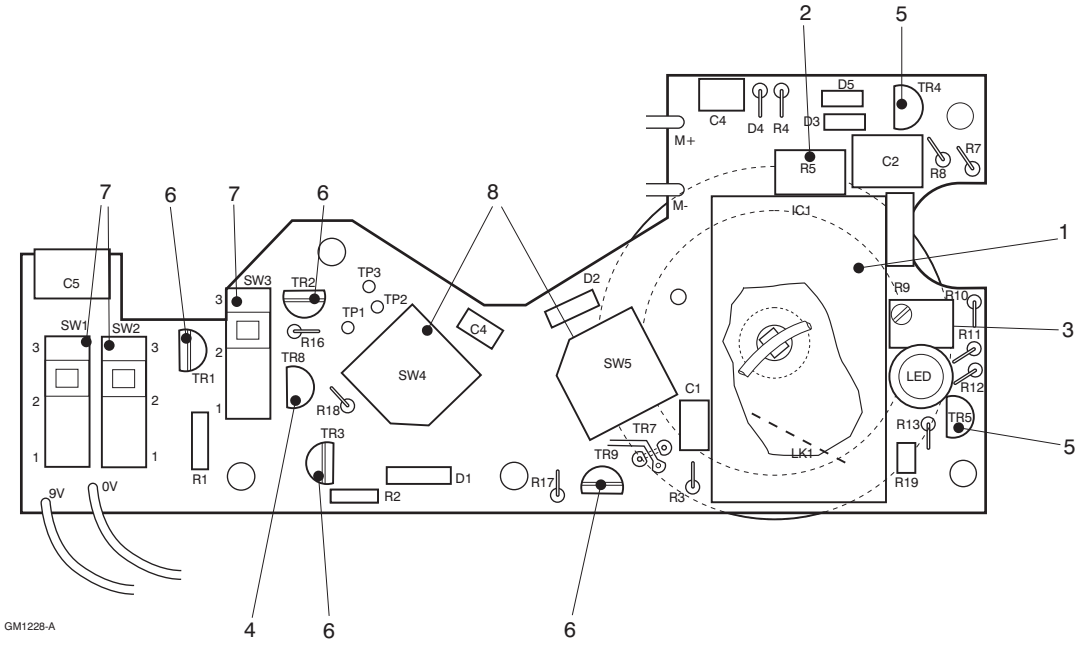


Figure 7-2 MS16A PCB assembly

Item No.	Description	Part Number
	PCB assembly	0105-0503
1	Custom IC	0105-0416
2	POT 50 ohms	2093-1040
3	POT 200 Kohms	2093-5240
4	Transistor BC184L	2450-2718
5	Transistor BC214L - 2 off	2455-2719
6	Transistor VN10KLS or VN10KM - 4 off	2462-4135
7	Microswitch - 3 off	3560-0021
8	Rotary switch - 2 off	3571-0000

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